House of Representatives

General Assembly

File No. 230

January Session, 2017

Substitute House Bill No. 7124

House of Representatives, March 27, 2017

The Committee on Insurance and Real Estate reported through REP. SCANLON of the 98th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING MAXIMUM ALLOWABLE COST LISTS AND DISCLOSURES BY PHARMACY BENEFITS MANAGERS, LIMITING COST-SHARING FOR PRESCRIPTION DRUGS AND SHIELDING PHARMACISTS AND PHARMACIES FROM CERTAIN PENALTIES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2017*) (a) As used in this section, (1) "maximum allowable cost" means the maximum amount a pharmacy benefits manager will reimburse a pharmacy for a prescription drug, and (2) "maximum allowable cost list" means a list of prescription drugs for which a maximum allowable cost has been established by a pharmacy benefits manager.

(b) (1) Each pharmacy benefits manager shall, prior to placing a prescription drug on a maximum allowable cost list, ensure that such drug (A) (i) has been designated as therapeutically equivalent to other pharmaceutically equivalent products with an "A" code or "B" code in the most recent edition or supplement of the federal Food and Drug

Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, or (ii) has an "NR" rating, "NA" rating or similar rating by a nationally recognized pricing reference, and (B) (i) is available for purchase by pharmacies in this state from national or regional wholesalers, and (ii) is not obsolete or temporarily unavailable. As used in this subparagraph, a drug is obsolete even if it is listed in national drug pricing compendia, if it is no longer actively marketed by the manufacturer or labeler.

(2) Each pharmacy benefits manager shall remove a prescription drug from a maximum allowable cost list not later than three business days after (A) the prescription drug no longer meets the requirements in subdivision (1) of this subsection, or (B) the pharmacy benefits manager becomes aware that such drug no longer meets the requirements in subdivision (1) of this subsection.

(c) Each contract entered into, renewed or amended on or after October 1, 2017, between a pharmacy benefits manager and a pharmacy or a pharmacy's contracting representative or agent shall disclose the sources used by the pharmacy benefits manager to determine the maximum allowable costs for prescription drugs on each maximum allowable cost list for such pharmacy.

(d) Each pharmacy benefits manager shall:

(1) Provide an updated maximum allowable cost list to a plan sponsor whenever there is a change to any such list under the plan;

(2) Update each maximum allowable cost list at least every seven calendar days and promptly notify and make available to each in-network pharmacy any such updated list applicable to such pharmacy; and

(3) Establish an appeals process for a pharmacy to contest the maximum allowable cost of a prescription drug in accordance with the provisions of subsection (e) of this section. Each pharmacy benefits manager shall provide to each in-network pharmacy information

concerning the appeals process.

(e) (1) A pharmacy may contest the maximum allowable cost of a prescription drug based on one or both of the following grounds:

(A) The prescription drug does not meet the requirements in subdivision (1) of subsection (b) of this section; or

(B) The maximum allowable cost established by the pharmacy benefits manager for the prescription drug is below the cost at which such drug is available for purchase from national or regional wholesalers.

(2) A pharmacy contesting the maximum allowable cost of a prescription drug shall file an appeal with the pharmacy benefits manager not later than sixty calendar days after filing its submission for the initial claim for reimbursement for such drug. The pharmacy benefits manager shall investigate and issue a determination of such appeal not later than seven calendar days after such manager receives such appeal.

(3) If the pharmacy benefits manager determines the appeal is denied, the manager shall provide to the pharmacy the reason for the denial and the national drug code of a therapeutically equivalent prescription drug that is available for purchase by pharmacies in this state from national or regional wholesalers at a price that is equal to or less than the maximum allowable cost for the prescription drug that is the subject of the appeal.

(4) If the pharmacy benefits manager determines the appeal is valid, such manager shall (A) adjust the maximum allowable cost for such prescription drug, and (B) adjust such maximum allowable cost for the appealing pharmacy not later than five business days after making such determination.

Sec. 2. Section 38a-510 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2018*):

(a) No insurance company, hospital service corporation, medical service corporation, health care center or other entity delivering, issuing for delivery, renewing, amending or continuing an individual health insurance policy or contract that provides coverage for prescription drugs may:

(1) Require any person covered under such policy or contract to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs; **[**or**]**

(2) Impose a coinsurance, copayment, deductible or other out-of-pocket expense that exceeds the claim cost of a covered prescription drug, except that a high deductible health plan, as that term is used in subsection (f) of section 38a-493, shall not be subject to the deductible provision set forth in this subdivision until after the minimum annual deductible for such plan has been met; or

[(2)**]** (3) Require, if such insurance company, hospital service corporation, medical service corporation, health care center or other entity uses step therapy for such drugs, the use of step therapy for any prescribed drug for longer than sixty days. At the expiration of such time period, an insured's treating health care provider may deem such step therapy drug regimen clinically ineffective for the insured, at which time the insurance company, hospital service corporation, medical service corporation, health care center or other entity shall authorize dispensation of and coverage for the drug prescribed by the insured's treating health care provider, provided such drug is a covered drug under such policy or contract. If such provider does not deem such step therapy drug regimen clinically ineffective or has not requested an override pursuant to subdivision (1) of subsection (b) of this section, such drug regimen may be continued. For purposes of this section, "step therapy" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition are to be prescribed.

(b) (1) Notwithstanding the sixty-day period set forth in subdivision **[**(2)**]** (3) of subsection (a) of this section, each insurance company,

hospital service corporation, medical service corporation, health care center or other entity that uses step therapy for such prescription drugs shall establish and disclose to its health care providers a process by which an insured's treating health care provider may request at any time an override of the use of any step therapy drug regimen. Any such override process shall be convenient to use by health care providers and an override request shall be expeditiously granted when an insured's treating health care provider demonstrates that the drug regimen required under step therapy (A) has been ineffective in the past for treatment of the insured's medical condition, (B) is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen, (C) will cause or will likely cause an adverse reaction by or physical harm to the insured, or (D) is not in the best interest of the insured, based on medical necessity.

(2) Upon the granting of an override request, the insurance company, hospital service corporation, medical service corporation, health care center or other entity shall authorize dispensation of and coverage for the drug prescribed by the insured's treating health care provider, provided such drug is a covered drug under such policy or contract.

(c) Nothing in this section shall (1) preclude an insured or an insured's treating health care provider from requesting a review under sections 38a-591c to 38a-591g, inclusive, or (2) affect the provisions of section 38a-492i.

(d) No individual health insurance carrier may terminate the services of, require additional documentation from, require additional utilization review, reduce payments or otherwise penalize or provide financial disincentives to any pharmacy or pharmacist on the basis that the pharmacy or pharmacist disclosed to an insured information concerning (1) the cost or efficacy of a prescription drug, or (2) any drug that is therapeutically equivalent to a prescription drug.

Sec. 3. Section 38a-544 of the general statutes is repealed and the

following is substituted in lieu thereof (*Effective January 1, 2018*):

(a) No insurance company, hospital service corporation, medical service corporation, health care center or other entity delivering, issuing for delivery, renewing, amending or continuing a group health insurance policy or contract that provides coverage for prescription drugs may:

(1) Require any person covered under such policy or contract to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs; **[**or**]**

(2) Impose a coinsurance, copayment, deductible or other out-of-pocket expense that exceeds the claim cost of a covered prescription drug, except that a high deductible health plan, as that term is used in subsection (f) of section 38a-493, shall not be subject to the deductible provision set forth in this subdivision until after the minimum annual deductible for such plan has been met; or

[(2)**]** (3) Require, if such insurance company, hospital service corporation, medical service corporation, health care center or other entity uses step therapy for such drugs, the use of step therapy for any prescribed drug for longer than sixty days. At the expiration of such time period, an insured's treating health care provider may deem such step therapy drug regimen clinically ineffective for the insured, at which time the insurance company, hospital service corporation, medical service corporation, health care center or other entity shall authorize dispensation of and coverage for the drug prescribed by the insured's treating health care provider, provided such drug is a covered drug under such policy or contract. If such provider does not deem such step therapy drug regimen clinically ineffective or has not requested an override pursuant to subdivision (1) of subsection (b) of this section, such drug regimen may be continued. For purposes of this section, "step therapy" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition are to be prescribed.

(b) (1) Notwithstanding the sixty-day period set forth in subdivision [(2)] (3) of subsection (a) of this section, each insurance company, hospital service corporation, medical service corporation, health care center or other entity that uses step therapy for such prescription drugs shall establish and disclose to its health care providers a process by which an insured's treating health care provider may request at any time an override of the use of any step therapy drug regimen. Any such override process shall be convenient to use by health care providers and an override request shall be expeditiously granted when an insured's treating health care provider demonstrates that the drug regimen required under step therapy (A) has been ineffective in the past for treatment of the insured's medical condition, (B) is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen, (C) will cause or will likely cause an adverse reaction by or physical harm to the insured, or (D) is not in the best interest of the insured, based on medical necessity.

(2) Upon the granting of an override request, the insurance company, hospital service corporation, medical service corporation, health care center or other entity shall authorize dispensation of and coverage for the drug prescribed by the insured's treating health care provider, provided such drug is a covered drug under such policy or contract.

(c) Nothing in this section shall (1) preclude an insured or an insured's treating health care provider from requesting a review under sections 38a-591c to 38a-591g, inclusive, or (2) affect the provisions of section 38a-518i.

(d) No group health insurance carrier may terminate the services of, require additional documentation from, require additional utilization review, reduce payments or otherwise penalize or provide financial disincentives to any pharmacy or pharmacist on the basis that the pharmacy or pharmacist disclosed to an insured information concerning (1) the cost or efficacy of a prescription drug, or (2) any

drug that is therapeutically equivalent to a prescription drug.

Sec. 4. Section 38a-479aaa of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2017*):

As used in this section and sections 38a-479bbb to 38a-479iii, inclusive, and section 1 of this act:

(1) "Commissioner" means the Insurance Commissioner;

(2) "Department" means the Insurance Department;

(3) "Drug" means drug, as defined in section 21a-92;

(4) "Person" means person, as defined in section 38a-1;

(5) "Pharmacist services" includes (A) drug therapy and other patient care services provided by a licensed pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, and (B) education or intervention by a licensed pharmacist intended to arrest or slow a disease process;

(6) "Pharmacist" means an individual licensed to practice pharmacy under section 20-590, 20-591, 20-592 or 20-593, and who is thereby recognized as a health care provider by the state of Connecticut;

(7) "Pharmacy" means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant pursuant to section 20-594; and

(8) "Pharmacy benefits manager" or "manager" means any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health benefit plan on behalf of plan sponsors such as self-insured employers, insurance companies, labor unions and health care centers.

Sec. 5. Section 38a-479hhh of the general statutes is repealed and the

following is substituted in lieu thereof (*Effective October 1, 2017*):

(a) The commissioner may conduct investigations and hold hearings on any matter under the provisions of sections 38a-479aaa to 38a-479iii, inclusive, as amended by this act, or section 1 of this act. The commissioner may issue subpoenas, administer oaths, compel testimony and order the production of books, records and documents. If any person refuses to appear, to testify or to produce any book, record, paper or document when so ordered, upon application of the commissioner, a judge of the Superior Court may make such order as may be appropriate to aid in the enforcement of this section.

(b) Any person aggrieved by an order or decision of the commissioner under sections 38a-479aaa to 38a-479iii, inclusive, as amended by this act, or section 1 of this act may appeal therefrom in accordance with the provisions of section 4-183.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2017*	New section
Sec. 2	*January 1, 2018*	38a-510
Sec. 3	*January 1, 2018*	38a-544
Sec. 4	*October 1, 2017*	38a-479aaa
Sec. 5	*October 1, 2017*	38a-479hhh

INS *Joint Favorable Subst.*

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

The bill is not anticipated to result in a fiscal impact to the state or municipalities as the bill does not alter the drugs covered on a plan's formulary, the cost sharing structure approved by the plans, or for the state, its generic substitution policy. The bill's cost sharing limitations and financial disincentive provisions are not anticipated to result in an impact as these are not practices of the state or municipal plans. The bill's requirements for a pharmacy benefit manager's (PBM) use of maximum allowable cost lists is not anticipated to result in a fiscal impact to the state as it regulates the relationship between the PBM and the pharmacy.

Lastly, the bill is not anticipated to result in a cost to the Department of Insurance to comply with the requirements of the bill as the agency has the expertise to do so.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis

sHB 7124

AN ACT CONCERNING MAXIMUM ALLOWABLE COST LISTS AND DISCLOSURES BY PHARMACY BENEFITS MANAGERS, LIMITING COST-SHARING FOR PRESCRIPTION DRUGS AND SHIELDING PHARMACISTS AND PHARMACIES FROM CERTAIN PENALTIES.

SUMMARY

This bill prohibits an individual or group health carrier (e.g., insurer or HMO) from imposing a coinsurance, copayment, deductible, or other out-of-pocket expense for a covered prescription drug that exceeds the drug's claim cost (§§ 2 & 3). The deductible prohibition does not apply to a high deductible health plan designed to be compatible with a federally qualified health savings account until after the plan's minimum annual deductible has been met.

The bill also prohibits health carriers from penalizing or providing financial disincentives to any pharmacy or pharmacist that discloses to an insured person information on (1) the cost or efficacy of a prescription drug or (2) a therapeutically equivalent drug (§§ 2 & 3). Prohibited actions include terminating services, requiring additional documentation or utilization review, and reducing payments.

Additionally, the bill establishes requirements for a pharmacy benefit manager's (PBM) use of maximum allowable cost (MAC) lists (§ 1). It sets criteria for a PBM to include a prescription drug on a MAC list and requires PBMs using MAC lists to (1) give certain disclosures about them to pharmacies and plan sponsors, (2) update the lists every seven days, and (3) establish an appeals process for pharmacies to contest a prescription drug's MAC. The bill authorizes the insurance commissioner to investigate a PBM's compliance with the MAC list requirements (§ 5). Anyone aggrieved by an order or decision of the commissioner may appeal to Superior Court.

Lastly, the bill makes a technical change (§ 4).

EFFECTIVE DATE: October 1, 2017 for the MAC list and technical provisions (§§ 1, 4 & 5) and January 1, 2018 for all other provisions (§§ 2 & 3).

PBM AND MAC LISTS

A "PBM" administers the prescription drug and pharmacy services portion of a health benefit plan on behalf of plan sponsors, including insurers, HMOs, labor unions, and self-insured employers.

A "MAC list" is a list of prescription drugs for which a PBM has set the maximum amount it will reimburse a pharmacy per prescription.

MAC List Criteria

Under the bill, a PBM may not place a prescription drug on a MAC list unless the PBM ensures that the drug has been:

1. designated as therapeutically equivalent to pharmaceuticals rated as an "A" or "B" drug in the U.S. Food and Drug Administration's most recent *Approved Drug Products with Therapeutic Equivalence Evaluations* publication or

2. given an "NR," "NA," or similar rating by a nationally recognized pricing reference.

Additionally, the PBM must ensure the drug is (1) available for purchase by Connecticut pharmacies from national or regional wholesalers and (2) not temporarily unavailable or obsolete (i.e., no longer actively marketed).

The bill requires a PBM to remove from a MAC list any prescription drug that no longer meets the above requirements. It must do so within three business days after the drug no longer meets the requirements or the PBM becomes aware of such fact.

Required Disclosures

The bill requires a PBM to:

1. include in any contract entered into, renewed, or amended on or after October 1, 2017 with a pharmacy (or its contracting representative or agent) the sources the PBM used to determine the MAC for prescription drugs included in each MAC list;

2. update each MAC list at least every seven days and promptly notify and make available to each in-network pharmacy any updated list applicable to it; and

3. give a plan sponsor an updated MAC list whenever a list under its plan changes.

PHARMACY APPEALS PROCESS

The bill requires a PBM to establish an appeals process for a pharmacy to contest a prescription drug's MAC. The PBM must give each in-network pharmacy (presumably those it contracts with) information about the appeals process.

Grounds for Appeal

Under the bill, a pharmacy may contest a MAC on one or both of the following grounds:

1. the prescription drug does not meet the criteria required for it to be included on the MAC list (see above) or

2. the PBM's MAC for the prescription drug is below the cost that a national or regional wholesaler charges for the drug.

Appeal Process

To contest a prescription drug's MAC, a pharmacy must file an appeal with the PBM within 60 days after filing its initial claim for reimbursement for the drug. The bill requires the PBM to investigate and issue a decision on the appeal within seven days after receiving it.

If the PBM denies the appeal, it must give the pharmacy the (1) reason for denial and (2) national drug code of a therapeutically equivalent prescription drug that Connecticut pharmacies can purchase from national or regional wholesalers at a price equal to or

less than the MAC for the drug that is the subject of the appeal.

If the PBM decides the appeal in favor of the pharmacy, it must adjust (1) the MAC for the drug that is the subject of the appeal and (2) the MAC for the appealing pharmacy within five business days after deciding the appeal.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Substitute
Yea 18 Nay 1 (03/09/2017)